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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/026,110

12/20/2001

Jill Cheng

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11/17/2004

AFFYMETRIX, INC

ATTN: CHIEF IP COUNSEL, LEGAL DEPT.

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EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,110

Applicant(s)

CHENG, JILL

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 8-12, 23-27 and 38-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13-22, 28-37 and 43-45 is/are rejected.
- 7) ☒ Claim(s) 4, 15, 19, 30 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Applicant's election of species (i) directed to orthologous genes, in the reply filed on 11/20/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8-12, 23-27 and 38-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/20/03.

It is recognized that the claim listing attached to the election/response of 11/20/03 was intended to be merely an indication of those claims that applicant considered to be elected, in an effort by applicant to fully reply to the election of species requirement. As no request to amend the claims accompanied the claim listing, the reply filed 11/20/03 is not considered by the examiner to be an actual amendment, and the Notice of nonresponsive amendment mailed 11/26/03 is hereby withdrawn.

An action on the merits of elected claims 1-7, 13-22, 28-37, and 43-45, as they read on the elected species, follows.

Information Disclosure Statement

It is noted that one or more references have been incorporated into the specification by reference, but have not been supplied to the PTO nor included in a properly filed IDS. Applicant is reminded that a listing of references in the specification

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is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. No IDS has been filed as of the date of this Office Action.

Drawings

The drawings are objected to because the dark shading of some boxes in Figures 4 and 5 render it impossible to determine what, if anything, is printed in the boxes. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because the second “sentence” is incomplete. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See e.g. pages 10, 15, and 19. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because of the following informalities: on page 17, line 3, the term “invneiton” should be --invention--. Appropriate correction is required.

Claim Objections

Claims 4, 15, 19, 30, and 45 are objected to because of the following informalities. In line 2 of each of claims 4 and 19, --the-- should be inserted before “selected”. Claims 15, 30, and 45 each recited the term “SQL”. The term is defined on page 10 of the specification as “Structured Query Language” and is therefore not indefinite. For greater clarity, however, the full term should be recited at least once in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 and 13-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are directed to a computer-implemented method, equivalent to mental steps. The claims do not recite any physical method step or transformation of data (i.e. no "safe harbor). In the absence of a physical method step or actual transformation of data, a computer-implemented method MAY be statutory where the claimed method recites a concrete, tangible, and useful result. See MPEP 2106.IV.B.1 and B.2.

The instant claims, in fact, do not recite any result. The claimed steps are directed to obtaining, selecting, and analyzing data, but do not recite any actual output or product from the analysis such that one skilled in the art would know what the result of the analysis IS. As no concrete, tangible and useful result is recited in the claim, the claims do not recite statutory subject matter. It is noted that claims 16-22, 28-37 and 43-45 are directed to man-made products and are thus considered statutory.

Claims 1-7, 13-22, 28-37 and 43-45 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well established utility.

The claims are directed to a method and computer system and computer-readable medium for running the method wherein the method recites steps of obtaining,

selecting, and analyzing gene expression data. The utility of the computer system and computer-readable medium rests on the utility of the method/program comprised therein. The instant specification does not disclose any utility for merely analyzing gene expression data. It is noted that a method which "finds" or outputs information regarding a correlation between gene expression data and particular "biological characteristics" MAY have a utility under 35 USC 101; however, the instant claims fail to recite any correlation step and the specification does not disclose any such step or "use" for the claimed method. On page 19, the specification discloses that in some embodiments the "analyzing" step includes selecting data for further analysis; i.e. the invention steps are apparently reiterated. Applicant is reminded that a "use" to perform further research on the invention itself is not a utility under 35 USC 101, and that a utility must be ascertainable without recourse to further experimentation. Applicant is reminded that the results of a method must be of "immediate benefit to the public" (See, e.g., *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (1966)). See MPEP 2107.

For the reasons set forth above, the claims are rejected as lacking utility.

Claims 1-7, 13-22, 28-37 and 43-45 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Specifically, one skilled in the art would not know what to "do" with the results of the analysis.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, 13-19, 21, 28-34, 36, and 43-45 are rejected under 35

U.S.C. 102(a) and (e) as being anticipated by ZHENG et al. (US 6,263,287).

ZHENG teaches a method, system, and program for manipulation and analysis of gene expression data wherein gene expression data is received/provided, and the data is clustered with regard to at least one biological characteristic, which may include tissue origin or genomic information about the gene (abstract and col. 2, lines 18-52), thereby anticipating claims 1-2, 4, 6, 16-17, 19, 21, 31-32, 34 and 36. ZHENG teaches use of SQL (col. 1, lines 61-63), thereby anticipating claims 15, 30 and 45. ZHENG teaches use of data from Genbank and other databases (col. 10), and teaches further analysis of the clustered data (col. 12, lines 40-45 and col. 15, lines 15-67), thus anticipating claims 3, 13-14, 18, 28-29, 33, and 43-44.

Claims 1-4, 6-7, 13-19, 21-22, 28-34, 36-37 and 43-45 rejected under 35

U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious

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over GARNER et al. (US 2003/0033290) and OGATA et al. (Nucleic acids Res. (1999) vol. 27, no. 1, pp. 29-34).

GARNER teaches a method, program and system for analysis of genetic databases (abstract) wherein gene expression data is obtained and clustered according to selected biological characteristics, including genomic information and biological function (paragraphs 8, 82 and 151-152), thereby anticipating claims 1-2, 4, 6, 16-17, 19, 21, 31-32, 34, and 36. GARNER teaches that the information derived from the clustering analysis may be used to select or recommend genes for further analysis (paragraph 257), thereby anticipating claims 3, 18, and 33. GARNER teaches a variety of databases (paragraph 158), including KEGG, and use of SQL software (paragraph 150), thereby anticipating claims 13-15, 28-30, and 43-45).

OGATA provides support that KEGG comprises information with regard to orthologous genes (p. 33, left column), therefore GARNER's teaching of KEGG is inherently a teaching for biological information comprising orthologous genes, and claims 7, 22, and 37 are anticipated and/or made obvious.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-6, 13-21, 28-36, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over ZHENG et al. (US 6,263,287) in view of ROCKE et al. (US 2002/0111742).

ZHENG teaches a method, program and computer system for analyzing gene expression data, as set forth above. ZHENG does not teach multiple dimension clustering.

ROCKE teaches classifying high dimensional data in methods of gene expression analysis (abstract and paragraph 85).

It would have been obvious to one of skill in the art at the time of invention to have performed the dimension reduction of ROCKE on large gene expression databases before clustering in the method of ZHENG where the motivation would have been to facilitate clustering and permit accurate "classification" of the data, as taught by ROCKE (paragraphs 7 and 17). One skilled in the art would reasonably have expected success in combining ROCKE's dimension reduction with ZHENG's clustering because both teach analyzing large amounts of gene expression data in order to correlate differential gene expression with tissue specificity (see ZHENG, col. 15 and ROCKE, paragraphs 85-86).

Conclusion

Claims 1-7, 13-22, 28-37 and 43-45 are rejected; claims 8-12, 23-27, and 38-42 are withdrawn. Claims 4, 15, 19, 30, and 45, the drawings and specification are all objected to.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
11/15/04